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WORLD INTELLECTUAL PROPERTY ORGANIZATION



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7:
A61N 1/375

(11) International Publication Number: WO 00/64535
(43) International Publication Date: 2 November 2000 (02.11.00)

(21) International Application Number: PCT/US00/03921
 (22) International Filing Date: 16 February 2000 (16.02.00)

(30) Priority Data: 09/299,704 26 April 1999 (26.04.99) US

(71) Applicant: ADVANCED NEUROMODULATION SYSTEMS, INC. [US/US]; Suite 100, 6501 Windcrest Drive, Plano, TX 75024 (US).

(72) Inventors: DAGLOW, Terry; 1005 Ashland Court, Allen, TX 75013 (US). LAURO, B., Reno; 413 Ridgeview Drive, Murphy, TX 75094 (US).

(74) Agents: COTROPIA, Charles, S. et al.; Sidley & Austin, Suite 3400, 717 N. Harwood, Dallas, TX 75201 (US).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

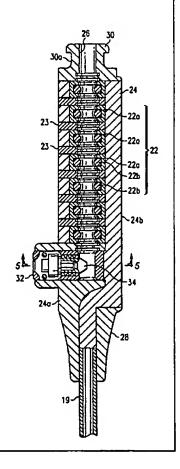
Published

With international search report.

(54) Title: LEAD CONNECTOR

(57) Abstract

A connector having a bore to receive a terminal end of a stimulation lead. The connector electrically contacts a received stimulation lead through one or more contacts. The contacts each have a readily deformable canted coil, which establishes a low resistance electrical connection with such received stimulation lead. The connector is adapted for use with lead extensions as well as incorporation into electrical energy sources, for example, a pulse generator.



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LEAD CONNECTOR

Field of the Invention

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The present invention relates to a lead connector, and particular, to a lead connector that receives an implantable stimulation lead with minimal insertion force and enables reliable contact with a received stimulation lead while reducing the labor required to secure such stimulation lead therein.

- 1 -

Background of the Invention

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To briefly describe a typical stimulation lead implantation procedure, a user first places a stimulation lead, whether through surgical intervention or otherwise, at a site to be stimulated. Depending on the intended result or condition, such site may generally be within the heart or the brain; along the spinal cord, peripheral nerves, sacral nerves; or more generally, in or about any tissue within the human body. Application of specific electrical energy to certain regions of the human body can effect a variety of physiological or psychological benefits, including symptomatolytic effects for a variety of conditions, for example, chronic pain, epilepsy, tremor, and urge incontinence.

To correctly position a stimulation lead, electrical energy is delivered through the stimulation lead during placement, and a practitioner guides the stimulation lead to a final placement position based on patient and/or physiological feedback. Once the stimulation lead is properly positioned, however, it becomes necessary to identify an optimized electrical energy that allows maximized symptomatolytic results. The burden of optimization is increased by both the potential variables of the delivered electrical energy (e.g., amplitude, frequency, pulse width, phase) and the number of electrodes of the stimulation lead—as each electrode can typically assume a positive polarity, a negative polarity, or an offstate. As but one example, an eight electrode stimulation lead can provide thousands of different electrode combinations, wherein each electrode combination may affect

differently the perceived nature of the delivered electrical energy.

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Understandably, identifying an optimum "setting" cannot generally be accomplished during a short evaluation. Rather, a trial is conducted for as little as a few days and as great as a few weeks. During this trial term, an implanted stimulation lead is typically connected to an external electrical energy source (e.g., pulse generator). This connection is commonly made via a temporary lead extension that connects the external electrical energy source to the implanted stimulation lead. The lead extension functions to deliver electrical energy to an implanted stimulation lead without having to expose the stimulation lead itself to an environment outside the body, thus protecting the patient from infection and other complications.

A conventional temporary lead extension includes a lead-like structure having a terminal end at a proximal end and a connector at a distal end. The terminal end is typically formed in accordance with a terminal end of a stimulation lead and, as provided above, is connectable to an electrical energy source. The connector features certain structure to receive a terminal end of an implanted stimulation lead and includes further structure to secure a received stimulation lead within the connector.

Lead extension connectors commonly take the form of set screw connectors. Set screw connectors include a housing, having a bore, that accommodates a plurality of set screws to establish an electrical connection with a received stimulation lead as well as retain such

stimulation lead within the connector. The plurality of set screws are arranged along a length of the connector and are movable between an exterior surface and the bore, thereby allowing each set screw to extend into, or retract from, the bore.

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As mentioned above, conventional stimulation leads can include a plurality of electrodes, for example, two, four, eight, sixteen, etc. As the set screws for this conventional connector are quite small, a user must be vigilant in initially loosening the set screws (i.e., to open the bore of the connector) not allow a set screw to become free of the connector. Once a stimulation lead is positioned within the bore, each set screw must be properly tightened to ensure contact with a received stimulation lead. Unless a torque wrench is used, care must be taken to limit the amount of force applied to each set screw to prevent damage to a received stimulation lead.

While the above example focuses on the role and burdens of conventional temporary lead extensions, permanent lead extensions, which are permanently implanted to connect an implanted stimulation lead to an implanted electrical energy source (e.g., a pulse generator), have largely the same structure and are subject to the same operational limitations. Moreover, the noted shortcomings of such set screw connectors are equally acknowledged as being a component of conventional electrical energy sources (e.g., pulse generators) which use such connectors to engage and retain stimulation leads, temporary lead extensions, and/or permanent lead extensions.

In reference to the known art of connectors, a need exists for a lead connector that requires minimal insertion force to receive a lead, allows a reliable, stable electrical connection with a received lead, and reduces the labor required to secure such lead therein.

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Summary of the Invention

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One aspect of the present invention is directed to a connector to engage a terminal end of a received stimulation lead for purposes of transferring electrical energy from an electrical energy source to terminals of the received the stimulation lead. The connector includes a housing having a bore. Positioned within the bore, a plurality of contacts, each being connectable to an electrical energy source and having a canted coil member, define in part a passage to receive a terminal end of a stimulation lead, wherein at least one contact of the plurality of contacts electrically engages a terminal of a received stimulation lead. The housing further accommodates a set screw that selectively engages a received stimulation lead to restrict longitudinal movement of such stimulation lead within the passage.

Another aspect of the present invention is directed to a lead extension having a plurality of terminals and a connector having a passage to receive a terminal end of a stimulation lead. The housing includes a plurality of contacts positioned along the passage, wherein each contact is electrically connected to a corresponding terminal of the plurality of terminals and includes a canted coil member, that are separated by at least one insulator to separate adjacent contacts. The housing further includes a set screw to selectively engage a received stimulation lead to restrict longitudinal movement of such stimulation lead within the passage.

An object of the present invention is to avoid the negative aspects of known connectors described above.

Another object of the present invention is to provide a lead connector that will establish a reliable, stable connection with a received terminal end of a lead.

Another object of the present invention is to provide a lead connector that will allow a received lead to be adequately secured therein to prevent inadvertent disconnection or movement of the terminal end of the implanted lead relative to the connector during operation.

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Another object of the present invention is to provide a connector contact that readily receives and contacts at least one terminal of a received lead through a low resistance interface.

Other aspects, objects, and advantages of the present invention will be apparent to those of ordinary skill in the art having reference to the following Specification together with the provided drawings.

Brief Description of the Drawings

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In reference to the following figures, like reference numerals and letters indicate corresponding elements:

- FIG 1 is a plan view of an implantable lead extension having a connector in accordance with the present invention;
- FIG. 2 is a partial sectional plan view of the connector of the lead extension of FIG. 1;
- FIG. 3 is a sectional side view of the connector of the lead extension of FIG. 1;
 - FIGS. 4A and 4B are sectional views of one embodiment of connector contacts in accordance with the present invention;
- FIG. 5 is sectional view of the connector of FIG. 2 along line V-V;
 - FIG. 6 is sectional view of a strain relief sleeve;
 - FIG. 7 is a perspective view of an implantable electrical energy device having a connector in accordance with the present invention; and
- FIG. 8 is a partial sectional view of the connector of FIG. 7 along line VIII-VIII.

Detailed Description of the Preferred Embodiments

Various embodiments, including preferred embodiments, will now be described in detail below with reference to the drawings.

FIG. 1 illustrates a preferred embodiment of lead extension 10. Lead extension 10 may functionally serve as a temporary lead extension or a permanent lead extension,

wherein the operational distinction between such structures is discussed in greater detail above. While the lead extensions illustrated and generally discussed here have a structure to connect with a stimulation lead having eight terminals, lead extension 10 can be readily modified by the teachings of this disclosure to accommodate a stimulation lead having any number of terminals.

Lead extension 10 includes a proximal end 12 and a distal end 14. The proximal end 12 includes a plurality of electrically conductive terminals 16, serially arranged along sheath 19, and the distal end 14 includes connector 20. In reference to FIG. 2, sheath 19 further encloses a plurality of conductors 18 that electrically connect each contact 22 of connector 20 to a respective terminal 16.

Sheath 19 is formed of a medical grade, substantially inert material, for example, polyurethane, silicone, or the like. While the specific material used for sheath 19 is not critical to the present invention, sheath 19 must be non-reactive to the environment of the human body, provide a flexible and durable (i.e., fatigue resistant) exterior structure for the conductors 18, and insulate adjacent terminals 16. Terminals 16 are preferably formed of a non-corrosive, highly conductive material. Examples of such material include stainless steel, MP35N, platinum, and platinum alloys. In a preferred embodiment, terminals 16 are formed of a platinum-iridium alloy.

While the specific assembly or construction of terminals 16, conductors 18, and sheath 19 is not a critical aspect of the present invention, in a preferred embodiment, these elements are assembled in accordance with the disclosure of co-pending application Ser. No.

09/xxx,xxx, filed on April 26, 1999. The disclosure of such application is accordingly incorporated by reference herein.

In reference to FIG. 3, connector 20 generally has a housing 24 that, in part, defines bore (or passage) 26. In a preferred embodiment, housing 24 is formed of a medical grade, substantially inert material, for example, polyurethane, silicone, or the like. When formed of an elastomer material, such as those provided here as an example, connector 20 becomes somewhat flexible along its longitudinal length. Consequently, when implanted within a patient, some patient discomfort that may otherwise be experienced can be alleviated by this flexible quality.

A proximal end of connector 20 includes strain relief 28, which engages sheath 19, and a distal end of connector 20 includes strain relief receiving element 30, which in part defines bore 26. Receiving element 30 can receive strain relief sleeve 31 (FIG. 6), wherein groove 30a would engage shoulder 31a when sleeve 31 is properly received. To ensure that sleeve 31 is retained with respect to connector 20, sleeve 31 is provided with suture groove 31b to operatively receive a suture (not shown). To assist in restricting (longitudinal) movement of a received stimulation lead (not shown) with respect to connector 20, an additional suture (not shown) can be applied about a distal portion 31c of sleeve 31. Of note, while sleeve 31 is shown having a smoothly tapered exterior surface, such exterior surface may include, for example, ridges (not shown) at or about the distal portion 31c to define an additional suture groove and/or be provided with a longitudinal slit (not shown) that extends along some

length of sleeve 31 that allows sleeve 31 to more completely collapse about an exterior surface of a received stimulation lead when subjected to a suture about the distal portion 31c. Notwithstanding the above examples referencing sleeve 31, sealing element 30 can directly receive a suture (not shown) to the exclusion of sleeve 31.

Bore 26 is largely defined by an alternating arrangement of insulators 23 and contacts 22. Each contact 22 is electrically joined to a conductor 18 that links such contact 22 with a corresponding terminal 16. As illustrated in FIG. 3, insulators 23 are formed as a part of housing 24; however, insulators 23 could be independent elastomer elements alternately assembled with contacts 22.

In addition to separating contacts 22, insulators 23 can be formed to sealingly engage an exterior surface of a received stimulation lead to prevent fluid penetration into connector 20. Insulators 23 of FIG. 3 are formed in such matter. It should be appreciated, however, that every insulator 23 does not have to be formed as a functional seal.

In one embodiment and in further reference to FIG. 4, each contact 22 is formed of annular housing 22a, which receives coil member 22b. Housing 22a is formed of a material having similar properties to that used to form terminals 16, specifically a non-corrosive, highly conductive material. In a preferred embodiment, annular housing 22a is formed of a platinum-iridium alloy or receives a platinum-iridium plating.

Each coil member 22b is formed from a single piece of spring wire having its proximal and distal ends joined. A

pattern of the spring wire may take a circular pattern, an elliptical pattern, sinusoidal pattern, or other geometric form. The spring wire is formed of a non-corrosive, highly conductive material that is subject to forming coil/spring structures (for example, stainless steel, MP35N, conductive elastomer materials, platinum/platinum-iridium alloy, or other material having a platinum/platinum-iridium alloy plating) and is compatible with the selected material of annular housing 22a. As should be appreciated, coil member 22b can take any variety of coil forms that satisfies the required functionality of this element. In a preferred embodiment, coil member 22b has 10-40 turns, and in a more preferred embodiment, coil member 22b has 20-40 turns. Each turn of coil member 22b provides almost an independent contact to electrically communicate with annular housing 22a.

Coil member 22b has an outer diameter sufficient to retain coil member 22b within annular housing 22a and an inner diameter of coil member 22b less than a diameter of a stimulation lead received within connector 20. Coil member 22b should be responsive to and allow passage of a terminal end of a stimulation lead through its inner diameter.

In a preferred embodiment, coil member 22b is a canted coil, see FIG. 4B. While a canted coil is appealing for the reproducible nature of its operational characteristics, the coil structure further offers performance advantages in its ability to accept a stimulation lead within its inner diameter. Specifically, a non-canted coil would increase the required insertion force necessary to position a stimulation lead within connector 26, as such force typically requires the deformation of the members (or

beams) that form such coil member 22b. Although such non-canted coil member 22b remains within the scope of the intended invention, it is not consistent with a most preferred embodiment of the present invention. Insertion of a stimulation lead through an inner diameter of coil member 22b, being formed of a canted coil merely requires the natural expansion of the coil form without beam deformation.

Preferably, coil member 22b is freely retained within the channel defined by annular housing 22a. To satisfy this preference, annular housing 22a and coil member 22b must be formed from materials that readily form a low resistance electrical connection through mere contact or when subjected to a minimal contact force. becomes necessary to look at the actual material interface between coil member 22b and annular housing 22a. In a preferred embodiment, such interface should include a minimal (i.e., thickness) or readily penetrable oxide layer (for example, as may exist between platinumiridium/platinum-iridium plated annular housing 22a and MP35N coil member 22b) or substantially no oxide layer (for example, as may exist between platinum-iridium/platinumiridium plated annular housing 22a and platinumiridium/platinum-iridium plated annular housing coil member 22b).

As an alternative embodiment, each contact 22 includes coil member 22a only, which is directly joined to a respective conductor 18.

Coil members 22b, while necessarily contacting a received stimulation lead, cannot be relied upon to apply retention-level forces, otherwise insertion of a

stimulation lead into connector 20 would be too difficult. Accordingly, as mentioned above, connector 20 can include set screw 34, accessible through set screw septum 32, to retain an inserted stimulation lead, see FIGS 3 and 5. While set screw 34 operatively contacts a terminal of a received stimulation lead for purposes of electrical communication, set screw 34 can be conductively non-functional, whereas set screw 34 would merely function to secure the received stimulation lead within connector 20. Set screw septum 32 is preferably positioned with respect to connector 20 so as to engage a proximal-most portion of an inserted stimulation lead. Alternatively, set screw septum 32 could be positioned closer to receiving element 30.

As mentioned, set screw 34 is used to retain a received stimulation lead within connector 20 to reduce an opportunity for longitudinal movement by such lead within bore 26. Set screw 34 can be used alone or in combination with sutures about distal portion 31c of sleeve 31, as discussed above. Moreover, when insulators 23 are formed so as to create seals with an exterior surface of a received stimulation lead, each seal imparts a retention force with respect to such lead. Accordingly, it should be further appreciated that use of a suture(s) about distal portion 31c of sleeve 31 (with or without sealing insulators 23) can eliminate the need for set screw 34 as well as set screw septum 32

While connector 20 is shown having a single bore 26, connector 26 could include two or more bores 26 (see generally, FIG. 7), wherein each bore 26 includes independent contacts 22, conductors 18, and set screws 34.

Moreover, while bore 26 has been generally shown to be annular, bore 26 can take assume any geometric shape to accommodate a shape of a terminal end of a stimulation lead.

The actual formation of housing 24 is not critical to the present invention. As illustrated in FIG. 3, housing 24 is shown as being formed in two injection operations: portion 24a in a first operations and portion 24b in a back-fill operation. Regardless, housing 24 could be formed by any process or in any number of steps/processes without departing from the teachings provided here.

Moreover, while the illustrative example of connector 20 is formed from an elastomer material, connector 20 could be formed of a housing having one or more rigid components.

Although the above discussion has been made in the context of connector 20 being apart of lead 10, in reference to FIGS. 7 and 8, it should be appreciated that the teachings here are equally applicable to a connector, integral or otherwise, for an implantable electrical energy device 200 (e.g., radio-frequency receiver, implantable pulse generator, etc.) that receives a terminal end of a stimulation lead. For this variation, conductors 18 would directly couple contacts 22 with the output of a pulse generator or other device that generates electrical energy for stimulation.

While the disclosed structures have been disclosed primarily in the context of receiving a stimulation lead, it should be appreciated by one having ordinary skill in this art that connector 20 has equal applicability to receiving a terminal end of a sensing lead.

While addressed in part above, as the invention has been described herein relative to a number of particularized embodiments, it is understood that modifications of, and alternatives to, these embodiments, such modifications and alternatives realizing the advantages and benefits of this invention, will be apparent to those of ordinary skill in the art having reference to this specification and its drawings. It is contemplated that such modifications and alternatives are within the scope of this invention as subsequently claimed herein, and it is intended that the scope of this invention claimed herein be limited only by the broadest interpretation of the appended claims to which the inventors are legally entitled.

What is claimed is:

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A connector to engage a terminal end of a received implantable lead for purposes of electrically communicating with the implantable lead, the connector comprising:

a housing defining a passage to receive a terminal end of a implantable lead;

at least one annular, canted coil member, positioned within the passage, to encompass at least a portion of a terminal end of a received implantable lead and to electrically contact a terminal of such implantable lead; and

a securing mechanism adapted to engage a received implantable lead to restrict longitudinal movement of such implantable lead within the passage.

- 1. A connector in accordance with Claim 1, wherein the at least one coil member is freely received within a conductive housing that electrically communicates with the at least one coil member.
- 2. A connector in accordance with Claim 2, further comprising at least one terminal, connectable to an electrical energy source, the at least one terminal being coupled to the conductive housing.
- 3. A connector in accordance with Claim 1, further comprising at least one sealing member within the passage to engage an exterior surface of a received implantable lead to prevent fluid intervention within the connector.
- 4. A connector in accordance with Claim 1, wherein an inner diameter of the at least one coil member is less than an outer diameter of a received implantable lead.
 - 5. A connector in accordance with Claim 1, wherein

the housing is formed of an elastomer material.

6. A connector in accordance with Claim 1, wherein the securing mechanism is a set screw.

- 7. A connector in accordance with Claim 1, wherein the securing mechanism is adapted to receive a suture to effect an engagement of a received implantable lead.
- 8. A connector in accordance with Claim 1, further comprising at least one terminal connectable to an electrical energy source, the at least one terminal is electrically coupled to the at least one coil member to allow electrical communication.
- 9. A connector to engage a terminal end of a received implantable lead for purposes of transferring electrical energy from an electrical energy source to terminals of the received implantable lead, the connector comprising:

housing having a bore; and

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a plurality of contacts, connectable to an electrical energy source and positioned within the bore, to in part define a passage to receive a terminal end of a implantable lead, wherein at least one contact of the plurality of contacts electrically engages a terminal of a received implantable lead;

wherein each contact includes a canted coil member.

- 10. A connector in accordance with Claim 10, further comprising a securing mechanism adapted to engage a received implantable lead to restrict longitudinal movement of such lead within the passage.
- 11. A connector in accordance with Claim 11, wherein the securing mechanism is a set screw.
 - 12. A connector in accordance with Claim 11, wherein

the securing. mechanism is. adapted to receive a suture to effect an engagement of a received implantable lead.

- 13. A connector in accordance with Claim 10, wherein each coil member is received and largely encompassed by a coil member housing, wherein the coil member is freely received within the coil member housing.
- 14. A connector in accordance with Claim 14, further comprising at least one terminal connectable to an electrical energy source, the at least one terminal being coupled to the conductive housing.
- 15. A connector in accordance with Claim 10, wherein an inner diameter of a coil member is less than an outer diameter of a received implantable lead.
- 16. A connector in accordance with Claim 10, further comprising at least one sealing member within the passage to engage an exterior surface of a received implantable lead to prevent fluid intervention within the connector.
- 17. A connector in accordance with Claim 10, wherein the housing is formed of an elastomer material.
- 18. A connector in accordance with Claim 10, further comprising a plurality of terminals connectable to an electrical energy source, the plurality of terminals being independently and electrically coupled to corresponding coil members to allow electrical communication.
 - 19. A lead extension comprising:
 a plurality of terminals; and

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- a connector having a passage to receive a terminal end of an implantable lead, including:
- a plurality of contacts positioned along the passage, wherein each contact is electrically connected to a corresponding terminal of the plurality of terminals; and

at least one insulator to separate adjacent contacts, wherein each contact has a canted coil member.

- 20. A lead extension in accordance with Claim 20, wherein the connector further comprises a securing mechanism adapted to engage a received implantable lead to restrict longitudinal movement of such lead within the passage.
- 21. A lead extension in accordance with Claim 21, wherein the securing mechanism is a set screw.
- 22. A lead extension in accordance with Claim 21, wherein the securing mechanism is adapted to receive a suture to effect an engagement of a received implantable lead.
- 23. A lead extension in accordance with Claim 20, wherein each coil member is received and largely encompassed by a coil member housing, wherein the coil member is freely received within the coil member housing:
- 24. A lead extension in accordance with Claim 20, wherein an inner diameter of a coil member is less than an outer diameter of a received implantable lead.
- 25. A lead extension in accordance with Claim 20, wherein an insulator of the at least one insulator is formed to sealingly engage an exterior surface of a received implantable lead.
- 26. An electrical stimulation device that delivers prescribed electrical energy through at least one connected, implantable lead, the device comprising:
- a controller to output prescribed electrical energy; and

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a connector, coupled to the controller to received the prescribed electrical energy, having a passage to receive a

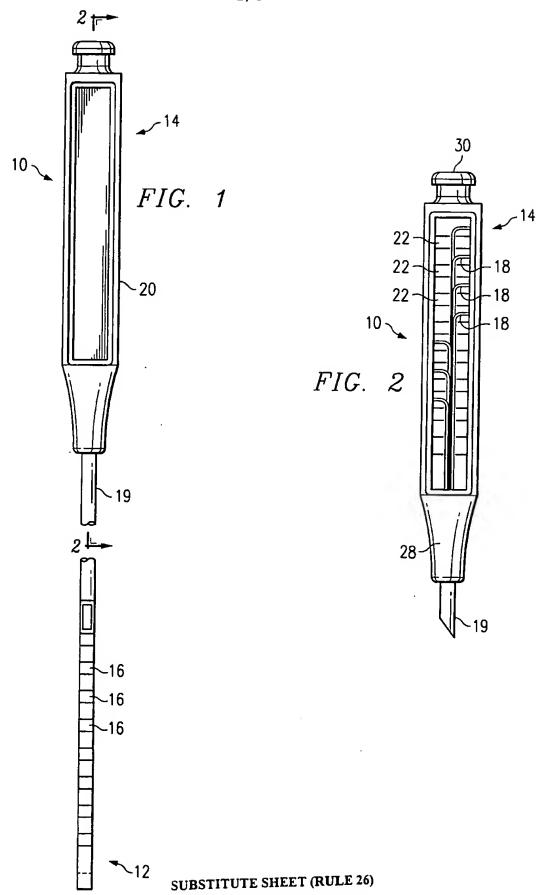
terminal end of an implantable lead, including a plurality of contacts positioned along the passage, wherein each contact is electrically connected to a corresponding terminal of the plurality of terminals,

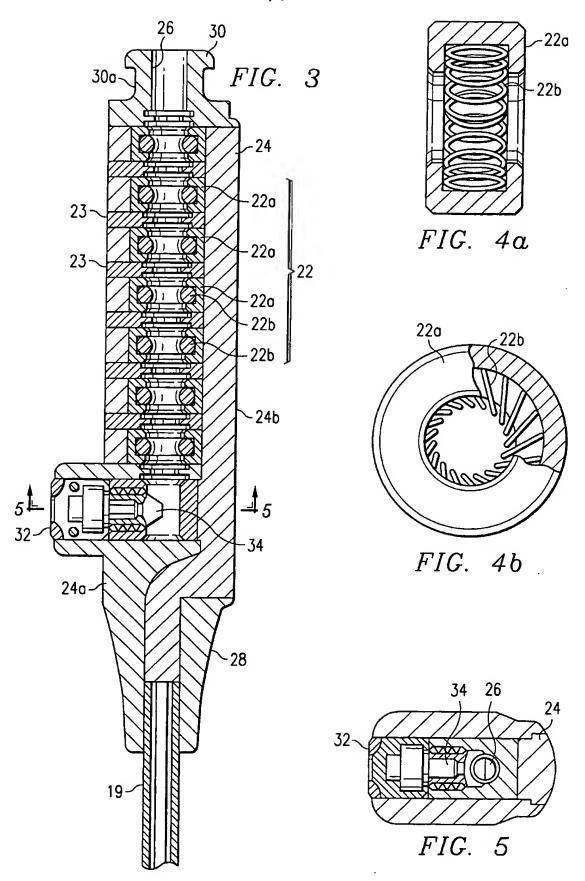
wherein each contact has a canted coil member.

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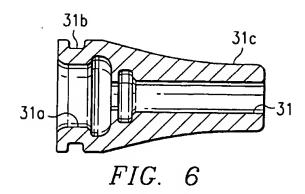
27. A device in accordance with Claim 27, further comprising at least one insulator to separate adjacent contacts.

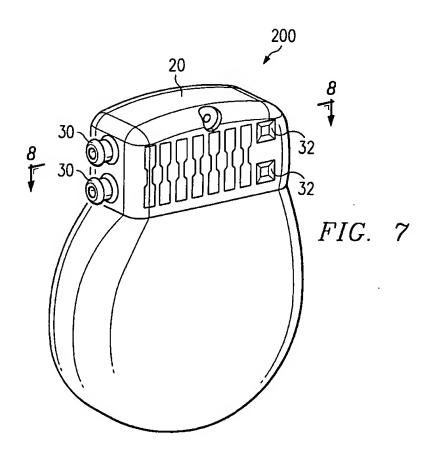
- 28. A device in accordance with Claim 28, wherein an insulator of the at least one insulator is formed to sealingly engage an exterior surface of a received implantable lead.
- 29. A device in accordance with Claim 27, wherein the connector further comprises a securing mechanism adapted to engage a received implantable lead to restrict longitudinal movement of such lead within the passage.
- 30. A device in accordance with Claim 30, wherein the securing mechanism is a set screw.
- 31. A device in accordance with Claim 30, wherein the securing mechanism is adapted to receive a suture to effect an engagement of a received implantable lead.
- 32. A lead extension in accordance with Claim 27, wherein each coil member is received and largely encompassed by a coil member housing, wherein the coil member is freely received within the coil member housing.
- 33. A lead extension in accordance with Claim 27, wherein an inner diameter of a coil member is less than an outer diameter of a received stimulation lead.
- 34. A lead extension in accordance with Claim 27, further comprising a pulse generator, coupled to the controller, to generate the prescribed electrical energy.

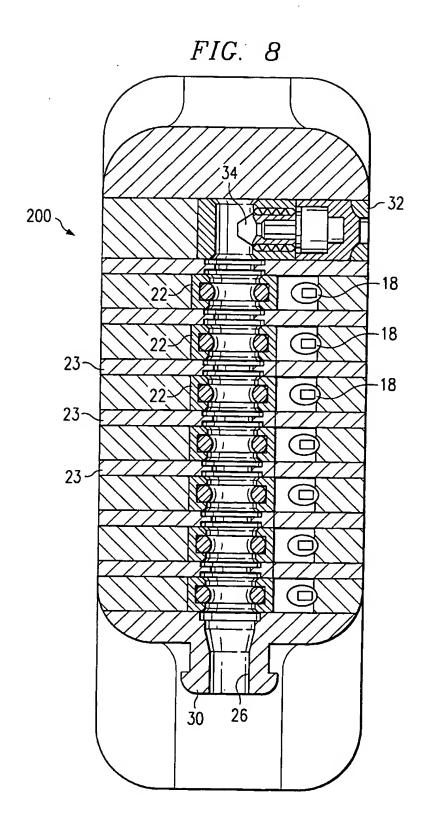




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INTERNATIONAL SEARCH REPORT

Inte Ional Application No PCT/US 00/03921

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C. DOCUM	ENTS CONSIDERED TO BE RELEVANT		
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